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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,802	02/09/2005	Mathias Locher	42804-212835	6177

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EXAMINER	
BROOKS, KRISTIE LATRICE	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,802	LOCHER ET AL.	
	Examiner	Art Unit	
	KRISTIE L. BROOKS	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 17-23 are pending. Claims 1-16 have been cancelled and claims 18-23 are new.

2. Receipt and consideration of Applicants remarks filed June 25, 2008 is acknowledged.

3. Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsig (US Pub No. 2003/0092706) in view of Hellberg et al. (US 6,452, 052).

Applicant claims a method for the treatment of respiratory diseases, allergic diseases, asthma, and/or chronic obstructive pulmonary diseases comprising the step of administering loteprednol or pharmaceutically acceptable ester thereof and N-(3,5-dicholopyridin-4-yl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3-yl]-2-oxoacetamide or a pharmaceutically acceptable sal thereof to a subject in need of treatment.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Barsig teaches the combined administration of a PDE4 or PDE3/4 inhibitors, such as N-(3,5-dicholopyridin-4-yl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3-yl]-2-oxoacetamide, also known as AWD-12-281, and disease modifying anti-rheumatic drugs (DMARDs) such as dexamethasone, prednisolone, budesonide, mometasone furoate, etc., for the treatment of diseases such as rheumatoid arthritis, acute or chronic (allergen-induced) airway disorders, allergic rhinitis/sinusitis, allergic skin diseases, etc. (see the abstract, page 1 paragraphs 1,17-18; page 2 paragraphs 19-22; page 3 paragraphs 30-32; page 4 paragraph 33; page 6 paragraphs 50-51). The combination is said to delay the onset and reduce the symptoms of rheumatoid arthritis (see page 1, paragraph 15). The medicaments containing the PDE inhibitor and the DMARD, either alone or in a fixed combination, are employed in the form of tablets, capsules, patches,

suppositories, suspensions or solutions either together or separately, and can be formulated with various excipients or vehicles suitable for desired pharmaceutical formulations (see page 6 paragraphs 50-53; page 7 paragraph 54). The combined use (i.e. simultaneous, sequential or separate administration) of PDE4 or PDE3/4 inhibitor and a DMARD may also include a medicament pack containing both the PDE4 or PDE3/4 inhibitor and a DMARD as discrete separate dosage forms and instructions for the simultaneous, sequential or separate administration of both discrete separate dosage forms (see the entire article, especially paragraphs 17-20 and claims 1-6).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Barsig does not teach the use of loteprednol etabonate in combination with a PDE4 or PDE3/4 inhibitor. This deficiency is cured by the teachings of Hellberg et al.

Hellberg et al. teach methods and compositions for treating allergic diseases, of the nose, skin, airway or lung by administering a disulfide derivative of formula (I) (see the abstract). The compounds can be administering win combination with an anti-inflammatory, such as, loteprednol, dexamethasone, prednisolone, etc., for the treatment of diseases, such as, allergic rhinitis, sinusitis, allergic disorders of the upper and lower airway, allergic disorders of the skin, etc. (see column 3 lines 24-53).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

One of ordinary skill in the art would have been motivated to do incorporate loteprednol into the combination taught by Barsig because loteprednol is known for use in combination with other drugs for the treatment of allergic and respiratory diseases as suggested by Hellberg et al.

Although Barsig do not teach loteprednol as a potential DMARD, loteprednol and DMARD agents such as dexamethasone, prednisolone, etc, are known to have the same anti-inflammatory action required for use on the same allergic diseases as suggested by Hellberg et al. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute loteprednol into the method taught by Barsig since it is an obvious variation of anti-inflammatory agents capable for use in the treatment of allergic and respiratory diseases taught by Barsig.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed composition.

Response to Arguments

Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie L. Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616